UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

HEALTHPOINT, LTD.,	)	
	)	
Plaintiff/Counter-defendant	)	
	)	
v.	)	CIVIL NO. SA-00-CA-0757-OG
	)	
ETHEX CORPORATION,	)	
	)	
Defendant/Counter-plaintiff	)	

FINDINGS OF FACT AND CONCLUSIONS OF LAW

This case was tried over a three-week period in September 2001. After hearing all the evidence, the jury deliberated for two days and returned their verdict on September 28, 2001. The parties filed post-trial motions in February-March 2002, and the Court has ruled on all such motions.

Having reviewed the record, the evidence presented at trial, the findings of the jury and the applicable law, the Court makes the following findings of fact and conclusions of law with regard to enhanced damages, attorneys' fees and equitable relief.

Findings of Fact

1. Healthpoint, Ltd. ("Healthpoint") is a Texas limited partnership having its principal place of business in San Antonio, Texas. DPT Laboratories, Ltd. ("DPT") is a Texas limited partnership having its principal place of business in San Antonio, Texas.

2. Healthpoint markets Accuzyme® ointment ("Accuzyme"), a product developed and manufactured by DPT. Accuzyme, a registered trademark owned by Healthpoint, is a

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prescription debriding ointment that uses a combination of papain, an enzyme derived from the papaya plant, and urea to digest dead tissue from necrotic wounds.

3. In 1995, DPT developed Accuzyme for Healthpoint by reverse-engineering Panafil White. The Rystan Company had been marketing Panafil White, a papain-urea ointment, for many years. However, Rystan was a very small company and its marketing was limited. Healthpoint concluded that a broader market for papain-urea ointment existed, and asked DPT to develop Accuzyme from Panafil White. In the process of reverse-engineering Panafil White, DPT tested Panafil White to determine its chemical makeup and stability. After formulating Accuzyme, DPT tested the product prior to its launch into the marketplace to determine its stability, safety and efficacy. The test procedure used to measure the ointment's efficacy was published in the peer-reviewed journal *Wounds*.

4. Healthpoint began marketing Accuzyme in 1996. Healthpoint used a large sales force, and successfully promoted the product nationwide. Healthpoint spent millions of dollars promoting Accuzyme, creating brand awareness and market acceptance. Within four years, the sales of Accuzyme increased from zero to $17.8 million. Accuzyme became the most prescribed papain-urea debriding ointment on the market.

5. Ethex Corporation is a Missouri corporation, having its principal place of business in St. Louis, Missouri. Ethex is a wholly-owned subsidiary of KV Pharmaceuticals, Inc. KV manufactures pharmaceutical products and markets those products through Ethex.

6. In 1998, KV began developing Ethezyme™, a papain-urea debriding ointment to compete with Accuzyme. In its own words, Ethex saw an opportunity to "piggy-back" on Accuzyme's success in the marketplace. By exploiting Accuzyme, Ethex projected that it could obtain a

substitution rate of nearly 100 percent. Ethex, with the assistance of a marketing agency, Trinity Communications, Inc., developed and launched a comparative advertising campaign.

7. Ethezyme was not tested for safety or efficacy prior or subsequent to its launch in June 2001. Although it had no test data to support a claim of comparable efficacy, Ethex wanted to demonstrate to consumers that Ethezyme was identical in composition to Accuzyme and thereby *imply* that the products had comparable efficacy.

8. Ethezyme was not and is not identical in composition to Accuzyme. Ethezyme contains substantially more papain and added stabilizers, including sodium metabisulfite. Ethex was aware of these differences in formulation before it launched Ethezyme. In fact, after speaking with Ethex, Trinity confirmed in a fax, dated June 29, 2000, that "we now know that Ethex cannot say that Ethezyme™ contains the identical active ingredients, "*in the same quantities*," as Accuzyme®."

9. Nevertheless, in June 2001, Ethex began marketing and selling Ethezyme nationwide in competition with and as a "generic substitute" for Accuzyme. Ethex widely advertised that Ethezyme contained the "same active ingredients in the same quantities as Accuzyme" even though it knew that such statement was false. Ethex also used terms such as "generic," "generic alternative," and "alternative" in a context which led the consumer to believe that the products were pharmaceutically equivalent. Ethex also stated that "[n]either brand nor generic papain-urea debriding compounds are subject to FDA approval rating," which created the false or misleading impression that Accuzyme was the "brand" and Ethezyme was the "generic." Ethex also offered special incentives (e.g. rebates and "two for one" deals) to promote the substitution of Ethezyme.

10. As a result of Ethex's false advertising claims, consumers believed that Ethezyme was generic to and substitutable for Accuzyme. Between January 2001 and July 2001, Ethex sold approximately 105,000 tubes of Ethezyme. These sales represent substitutions for and lost sales of Accuzyme. Wound care clinicians and other medical professional testified that they tried using Ethezyme because they understood it was the same as Accuzyme. However, based on their personal experiences, Ethezyme was not as effective as Accuzyme.

11. There is clear and convincing evidence to support the jury's findings of bad faith and willful, deliberate and malicious misconduct. Ethex made a conscious decision to market its product with prior knowledge that its advertising statements were false and would cause substantial injury to Healthpoint. Ethex was marketing a debriding ointment that would be prescribed by physicians, dispensed by pharmacists and used by healthcare professionals around the nation. Ethex's conduct in this case was egregious.

12. Healthpoint's sales and market share have suffered and its reputation and goodwill have been damaged. Healthpoint has expended substantial time and resources to correct confusion in the marketplace and to maintain consumer confidence in papain urea debriding ointment.

Conclusions of Law

1. The Court has jurisdiction over the parties and the subject matter of this lawsuit.

2. As found by the jury, Ethex is liable to Healthpoint for false advertising under Section 43(a) of the Lanham Act. Ethex made literally false statements and misleading statements that were material and either deceived or had the tendency to deceive consumers. Specifically, Ethex's statement that Ethezyme had the "same active ingredients in the same quantities" as Accuzyme was literally false. Other statements that included terms or phrases such as

"alternative", "generic alternative" or "neither brand nor generic papain-urea debriding compounds are subject to FDA approval or rating" were at least misleading in the context presented and actually deceived or had the tendency to deceive consumers.

3. Ethex is liable to Healthpoint for unfair competition under the Lanham Act as found by the jury. Ethex's promotional campaign depended almost exclusively on the strength and quality of Accuzyme, a successful debriding ointment, and the goodwill of Healthpoint, an established wound care company. The product names (Accuzyme and Ethezyme) were similar, and the target audience was the same. The statements made by Ethex were likely to cause confusion about the similarity between the products and whether Ethezyme was a "generic alternative" and appropriate substitute for Accuzyme. Moreover, the statements caused actual confusion about the origin or source of Ethezyme and whether Ethex and Healthpoint were affiliated.

4. Ethex is liable to Healthpoint and DPT for misappropriation as found by the jury. Although Healthpoint owns the trademark, DPT invested extensive time, labor, skill and money in the successful development of Accuzyme. Ethex misappropriated Accuzyme's name and reputation, as well as Healthpoint's reputation and goodwill by using comparative advertisements that were false and/or misleading. By using Accuzyme to promote its own product, Ethex avoided the costs of research and development and gained an unfair advantage in the marketplace.

5. Ethex is liable to Healthpoint for unfair competition under state law. To recover on a claim of unfair competition, there must be evidence of an independent substantive tort. Such evidence exists in this case. An affirmative jury finding on false advertising, standing alone, would support a finding of unfair competition under state law.

6. As found by the jury, Healthpoint is entitled to actual damages in the amount of $5,000,000.00. Mr. Escobedo's damage estimate, based on incremental cost analysis, was $3,498,905.00 for the period July 2000 through June 2001. Mr. Locey testified that Healthpoint sales for the year 2000 was about one million dollars lower than projected, and sales for the year 2001 would be at least five million dollars less than projected. He also testified that such losses had never occurred in the past. Because other theories on the cause of such losses were never fully explored, and the evidence is consistent with Healthpoint's theory, the jury reasonably inferred, based on all the evidence, that such losses were the result of Ethezyme's introduction into the market and promotion thereof.

7. Healthpoint is entitled to those profits that Ethex enjoyed as a result of false advertising and unfair competition. 15 U.S.C. § 1117(a). The sum of such profits is $1,640,000.00, as found by the jury. When viewing the evidence in its entirety, there is no doubt that Ethex benefitted from false and/or misleading advertisements. By its own admission, the success of its advertising campaign was dependent upon a showing that Ethezyme was the same as, or a generic alternative to Accuzyme. Such advertisements diverted sales from Accuzyme, and resulted in sales of Ethezyme that would not have occurred otherwise.

8. Healthpoint is entitled to punitive damages in the amount of $3,174,515.00, as found by the jury. Ethex made a deliberate choice to make representations about its product that were false, knowing that such representations would cause substantial injury to Healthpoint. Thus, an award of punitive damages is warranted, and the amount awarded by the jury is reasonable.

9. The jury recommended additional or enhanced damages in the amount of $6,349,030.00. The jury's finding is merely advisory, and the Court has the discretion to determine the amount

of enhanced damages, if any. See 15 U.S.C. § 1117(a). The evidence clearly shows that Ethex engaged in knowing and intentional conduct. Ethex made false and misleading statements knowing that consumers would be harmed (or at least misled) and that Healthpoint would suffer commercial losses. The jury's award of actual damages will not completely compensate Healthpoint for the losses and expenses which it has incurred and will continue to incur. Thus, the Court finds that enhanced damages are appropriate, and adopts the jury's finding as an appropriate sum.

10. The total amount of damages to be awarded to Healthpoint is $16,163,545.00.

11. DPT is entitled to actual damages in the amount of $350,000, as found by the jury.

12. The Lanham Act specifically provides for the assessment of costs as part of the damages calculation. 15 U.S.C. § 1117(a). Thus, costs of this action, as defined by 28 U.S.C. § 1920, shall be taxed against Ethex Corporation. The costs awarded to Healthpoint and DPT should not be duplicative.

13. Both Healthpoint and DPT are entitled to post-judgment interest of the sums awarded to them.

14. The Court finds that this is an "exceptional" case warranting an award of attorneys' fees under the Lanham Act. 15 U.S.C. § 1117(a). Attorneys' fees may be awarded to Healthpoint only.

15. Healthpoint is entitled to permanent injunctive relief. Although Ethex contends that the deceptive and/or misleading advertising has ceased, there is certainly no guarantee that it will *not* happen again. Moreover, Ethex will not be inconvenienced by the Court's order to the extent that it has ceased such advertisements, while Healthpoint is likely to suffer irreparable injury if

such advertisements recur in the future. Injunctive relief will also serve the public interest.

Specifically, Healthpoint is entitled to a permanent injunction restraining Ethex and its officers, agents, servants and representatives from advertising, promoting or marketing Ethezyme as a "generic" or as an "alternative" or "generic alternative" to Accuzyme; and, from advertising, promoting or marketing Ethezyme as having the "same active ingredients in the same quantities" as Accuzyme; and, from using the statement that "neither brand nor generic papain-urea compounds are subject to FDA approval or rating" or other similar terms or phrases which create the false or misleading impression that Accuzyme is the "brand" and Ethezyme is a "generic" substitute for Accuzyme.

16. The jury concluded that Healthpoint and DPT should not be barred or estopped from obtaining relief, equitable or otherwise, and the Court agrees.

17. The Court agrees with the jury's finding that Ethex is guilty of unclean hands and should be estopped from obtaining any relief.

18. Based on the jury's findings and the evidence at trial, Ethex is not liable for any claims asserted by DFB Pharmaceuticals, Inc.

19. Based on the jury's findings, the evidence at trial and the applicable law, KV Pharmaceuticals, Inc. is not liable for any claims asserted by DPT and DFB.

20. Based on the jury's findings and the evidence at trial, Healthpoint, Ltd. is not liable for any claims asserted by Ethex.

21. Based on the jury's findings and the evidence at trial, DPT is not liable for any claims asserted by Ethex.

22. Based on the jury's findings and the evidence at trial, DFB is not liable for any claims asserted by Ethex.

23. Based on the jury's findings and the evidence at trial, Ethex is not entitled to permanent injunctive relief.

Any finding of fact that should be more properly considered a conclusion of law, and any conclusion of law that is more properly considered a finding of fact, should be so considered.

SIGNED and ENTERED this 10 day of December, 2002.

ORLANDO L. GARCIA
UNITED STATES DISTRICT JUDGE